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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,430	11/20/2003	Masanobu Sugawara	011392A	6955

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EXAMINER

FREISTEIN, ANDREW B

ART UNIT PAPER NUMBER

1626

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,430

Applicant(s)

SUGAWARA ET AL.

Examiner

Andrew B. Freistein

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/926,346.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-68 are currently pending in the instant application.

Priority

This application is a Divisional application of US Application 09/926,346, filed 02/25/2002, which granted as US Pat. No. 6,720,449, which is a 371 of PCT/JP01/01132, filed 02/16/2001.

Acknowledgement is made of Applicant's claim for foreign priority under 35 USC § 119(a)-(d) of Japan patent application P2000-039415, filed 02/17/2000 and Japan patent application P2000-334391, filed 11/01/2000.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. **Claims 1-3**, drawn to a process for producing an optically active N-protected-aziridine-2-carboxylic acid of Formula (3).
- II. **Claims 4-6**, drawn to a process for producing an optically active N-protected-aziridine-2-carboxylic acid of Formula (3).
- III. **Claims 7-15 and 26-34**, drawn to an optically active amino acid derivative represented by formula (6).
- IV. **Claims 16-25**, drawn to a process for producing an optically active amino acid derivative represented by formula (6).
- V. **Claims 35-42**, drawn to a process for producing an optically active amino acid represented by formula (6).

- VI. **Claims 43 and 44**, drawn to the process of preparing the metal acetylide of Claim 23 represented by formula (8).
- VII. **Claims 45-47**, drawn to a process for producing an optically active aziridine-2-carboxylic acid derivative using an optically active 3-haloalanine derivative represented by formula (1).
- VIII. **Claims 48-49**, drawn to a process for producing an optically active aziridine-2-carboxylic acid derivative using an optically active 3-haloalanine derivative represented by formula (1).
- IX. **Claim 50**, drawn to a process for producing an optically active N-protected-aziridine-2-carboxylic acid of Formula (3).
- X. **Claims 51-52**, drawn an optically active N-protected-aziridine-2-carboxylic acid of Formula (3).
- XI. **Claims 53-56**, drawn to an optically active amino acid derivative represented by formula (9).
- XII. **Claims 57-63**, drawn to a process for crystallizing a compound represented by formula (6).
- XIII. **Claims 64-68**, drawn to a process for crystallizing a compound represented by formula (6).

Rational Establishing Patentable Distinctiveness Within Each Group

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects

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and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are presumed patentable over each other. Chemical structures that are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to be function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of ***Application of Papesch***, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and ***In re Lulu***, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

Invention I, Invention II and Invention IX are each drawn to a process for producing an optically active N-protected-aziridine-2-carboxylic acid of Formula (3). Invention I differs from Invention II in that Invention I comprises subjecting an optically active 3-haloalanine derivative of Formula (1) to an intramolecular cyclization reaction in the presence of a base to form an optically active aziridine-2-carboxylic acid derivative of Formula (2). On the other hand, Invention II comprises protecting the amino group of an optically active 3-haloalanine derivative of Formula (1) to give an optically active N-

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protected-3-haloalanine derivative of Formula (4). Furthermore, Invention IX differs from Invention I and II in that the process of Invention IX is characterized by treating an optically active aziridine-2-carboxylic acid derivative of formula (2) with benzenesulfonyl chloride.

Inventions III, IV and V are each drawn to a process for producing an optically active amino acid derivative represented by formula (6). Invention III treats an optically active N-protected-aziridine-2-carboxylic acid of formula (3) with an organic metal reagent of formula (5). On the other hand, Invention IV comprises protecting the amino group of an optically active 3-haloalanine derivative of formula (1) to give an optically active N-protected-3-haloalanine of formula (4), then treating it with an organic metal reagent of formula (5). Invention V comprises treating an optically active N-protected-3-haloalanine derivative of formula (4) with an organic metal reagent of formula (5). Since Inventions III, IV, and V have varying steps in their respective processes, they are patentably distinct inventions.

Invention VI is drawn to a process for preparing a metal acetylide represented by formula (8). Invention VI depends on Claim 23 of Invention IV, but differs from Invention IV, because Invention VI is drawn to the production of the metal acetylide of formula (8) by treating an optically protected 3,3-dimethylpropargylamine for formula (10). On the other hand, Invention IV is the production of an optically active amino acid derivative represented by formula (6).

Inventions VII and VIII are each drawn to a process for producing an optically active aziridine-2-carboxylic acid derivative using an optically active 3-haloalanine

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derivative represented by formula (1). However, the process of Invention VII uses an alkali metal hydroxide or an alkaline earth metal hydroxide as the base, whereas the process of Invention VIII uses an amine as the base.

Invention X and Inventions I, II and IX are related as product and process of preparation. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP 806.04, MPEP 808.01). In the instant case the inventions are drawn to distinct methods of preparing distinct compounds, which will use different starting materials, reagents, and reaction conditions as illustrated on pages 61-85 of the Specification.

Invention XI is drawn to an optically active amino acid derivative represented by formula (9). This product differs from the other products in that it does not contain an aziridine, creating patentably distinct products, which require a separate prior art search.

Inventions XII and XIII are each drawn to a process for crystallizing a compound of formula (6). The process of Invention XII is characterized by neutralizing with an acid aqueous solution containing an N-protected optically active amino acid derivative salt represented by the formula (6). However, the process of Invention XIII is characterized by salting out with a halogenated alkali metal salt an aqueous solution containing an alkali metal salt of an optically active amino acid derivative represented by formula (6).

In addition, due to the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of the application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of the claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claims remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Andrew B. Freistein
Patent Examiner, AU 1626

for Kamal Saeed
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Supervisory Patent Examiner, AU 1626
Date: October 5, 2005